

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

TRANSLATION

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing **See form PCT/ISA/210**
(day/month/year)

Applicant's or agent's file reference
0000055277

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/EP2005/000312

International filing date (day/month/year)

14.01.2005

Priority date (day/month/year)

22.01.2004

International Patent Classification (IPC) or both national classification and IPC

A61K7/02, A61K7/42, A61K7/48

Applicant

BASF AKTIENGESELLSCHAFT

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/EP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I	Basis of this opinion
1.	<p>With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.</p> <p><input type="checkbox"/> This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).</p>
2.	<p>With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:</p> <p>a. type of material</p> <p><input type="checkbox"/> a sequence listing</p> <p><input type="checkbox"/> table(s) related to the sequence listing</p> <p>b. format of material</p> <p><input type="checkbox"/> in written format</p> <p><input type="checkbox"/> in computer readable form</p> <p>c. time of filing/furnishing</p> <p><input type="checkbox"/> contained in the international application as filed.</p> <p><input type="checkbox"/> filed together with the international application in computer readable form.</p> <p><input type="checkbox"/> furnished subsequently to this Authority for the purposes of search.</p>
3.	<p><input type="checkbox"/> In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.</p>
4.	<p>Additional comments:</p>

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Box No. II

Priority

1. ☐ The following document has not yet been furnished:
- ☐ copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).
- ☐ translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).
- Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date in the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:
- The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.

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Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims 4, 6, 11

YES

Claims 1-3, 5, 7-10, 12

NO

Inventive step (IS)

Claims

YES

Claims 1-12

NO

Industrial applicability (IA)

Claims 1-12

YES

Claims

NO

2. Citations and explanations:

- 1) The following documents D1-D5 cited in the international search report are mentioned in this opinion. The same numbering will be used throughout the procedure:

D1 = US-A-2001/055597

D2 = US-A-6,080,393

D3 = US-A-2002/123460

D4 = US-A-2002/110572

D5 = EP-A-0 440 398

- 2) The present application does not meet the requirements of PCT Article 33(1) because the subject matter of independent claim 1 is not novel within the meaning of PCT Article 33(2).
Examples 9B and 31J of document D1 disclose preparations comprising (a) retinol (10% or 45% active), (b) 0.1% by weight sodium metabisulphite or ascorbic acid as water-soluble antioxidant, (c) 0.05% by weight butylated hydroxytoluene (BHT) as oil-soluble antioxidant and (d) 6.0% by weight octylmethoxycinnamate as UV filter. The weight ratios between (a) and (b), and (a) and (c) fall

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within the claimed ranges (example 9B: $(b)/(a) = 2.17$ and $(c)/(a) = 1.09$; example 31J: $(b)/(a) = 1.31$ and $(c)/(a) = 0.65$).

Examples 9A and 9B of document D2 disclose preparations comprising (a) retinol (10% active), (b) 0.1% by weight sodium metabisulphite as water-soluble antioxidant, (c) 0.05% by weight butylated hydroxytoluene (BHT) as oil-soluble antioxidant and (d) 6.0% by weight titanium dioxide or octylmethoxycinnamate as UV filter. The weight ratios between (a) and (b), and (a) and (c) fall within the claimed ranges ($(b)/(a) = 2.17$ and $(c)/(a) = 1.09$).

- 3) Dependent claims 2, 3, 5, 7-10 and 12 do not contain any features which, in combination with the features of any claim to which they refer, meet the PCT requirements for novelty over D1 or D2.
- 4) The present application also does not meet the requirements of PCT Article 33(1) because the subject matter of independent claim 1 is not inventive within the meaning of PCT Article 33(3).

The object of the present application is to provide retinoid-containing preparations which do not display disadvantages in relation to stability and discoloration and which are easy to manufacture.

This object was achieved by stabilizing retinoids by using water-soluble antioxidants and oil-soluble antioxidants in particular concentration ranges.

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According to the application it is essential to comply with certain weight ratios between the retinoids and the water-soluble antioxidants and oil-soluble antioxidants. Also important is the content of one or more water-soluble antioxidants (in the range from 0.05 to 0.8% by weight) and that the preparation additionally comprises 0.01 to 10% by weight of at least one UV filter.

However, no evidence is provided in the present application (with the aid of comparative examples) showing why specifically the claimed concentration ranges and weight ratios lead to better results. The description is confined to the composition, without measuring the stability thereof. Moreover, the effect of the UV filter in solving the technical problem is not made clear in the application. Is/Are the UV filter(s) used to stabilize retinoids or only to protect the human skin from UV radiation? Once again, no evidence is provided.

Documents D1 to D5 all describe the use of water-soluble and oil-soluble antioxidants for stabilizing retinoids. Examples 1-4, 6, 10, 12, 13-III, 13-IV, 14 and 31I of document D1 differ from the subject matter of independent claim 1 either by the preparations containing no UV filter and/or by the weight ratio between the retinoid and the water-soluble antioxidant being not greater than 1. The same applies to examples 1, 1A, 2-4, 6-V, 10, 12, 13-III and 13-IV of document D2. Examples 6-9, 14 and 15 of document D3 differ from the subject matter

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of independent claim 1 either by the preparations containing no UV filter and/or by the content of one or more water-soluble antioxidants being greater than 0.8% by weight. The examples in tables 1-3 of document D4 differ from the subject matter of independent claim 1 only in that the preparations contain no UV filter. Examples I-IX, XIII-XVII and XX-XXIV of document D5 differ from the subject matter of independent claim 1 only by the preparations containing no UV filter and/or by the weight ratio between the retinoid and the water-soluble antioxidant being not greater than 1. As already mentioned above, no evidence is provided to show that these particular concentration ranges and weight ratios lead to better results and that the use of a UV filter contributes to solving the problem. UV filters are anyway mentioned as conventional adjuvants in all of documents D1-D5. It would be obvious to a person skilled in the art, without being inventive, to include UV filters in the preparations for protecting the human skin from UV radiation. The concentration ranges and weight ratios of claim 1 represent a selection from the ranges described in documents D1-D5. However, such a selection can be regarded as inventive only if unexpected effects or properties are associated therewith. Such effects or properties are, however, not indicated in the application. The subject matter of independent claim 1 therefore does not involve an inventive step.

5) Claims 2-12 do not contain any features which, in

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combination with the features of any claim to which they refer, meet the PCT requirements for inventive step.

- 6) Claims 1-12 satisfy the criterion specified in PCT Article 33(4) because the present invention is industrially applicable in the washing compositions sector.

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Box No. VI

Certain documents cited

1. Certain published documents (Rule 43bis.1 and 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO-2004/012696	12.02.2004	16.07.2003	24.07.2002

See supplemental sheet

2. Non-written disclosures (Rule 43bis.1 and 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)
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See form 210

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

- 1) Contrary to PCT Rule 5.1(a)(ii), the description
does not cite documents D1-D4 and D6 or indicate the
relevant prior art disclosed therein.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box VI

This document (D6) does not belong to the prior art pursuant to PCT Rule 64.3 but might become prior art in accordance with Article 54(3) EPC in the regional phase before the EPO.

Examples 2, 3, 8 and 9 of document D6 describe preparations comprising (a) retinol 15D (15% active), (b) sodium ascorbate or ascorbic acid as water-soluble antioxidant, (c) tocopherol as oil-soluble antioxidant and (d) octylmethoxycinnamate or benzophenone-3 as UV filter. The weight ratios between (a) and (b), and (a) and (c) fall within the claimed ranges (example 2: $(b)/(a) = 3.0$ and $(c)/(a) = 6.1$; example 3: $(b)/(a) = 4.0$ and $(c)/(a) = 20.2$; example 8: $(b)/(a) = 2.0$ and $(c)/(a) = 5.1$; example 9: $(b)/(a) = 2.0$ and $(c)/(a) = 0.2$). The subject matter of present claims 1-3 and 5-12 was therefore disclosed in D6.